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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,765	04/22/2005	Serge Louis Boulet	X-15991	4914
25885	7590	11/29/2007	EXAMINER	
ELI LILLY & COMPANY			SOLOLA, TAOFIQ A	
PATENT DIVISION				
P.O. BOX 6288			ART UNIT	
INDIANAPOLIS, IN 46206-6288			PAPER NUMBER	
			1625	
			NOTIFICATION DATE	
			DELIVERY MODE	
			11/29/2007	
			ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

Office Action Summary

Application No.

10/532,765

Applicant(s)

BOULET ET AL.

Examiner

Taofiq A. Solola

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 23 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 6, 7, 22 and 34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 6, 7, 22 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Claims 6-7, 22, 34 are pending in this application.

Claims 1-5, 8-21, 23-33 are cancelled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-7, 22, 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shephard et al., GB 2,060,622 A, in view of King, Med Chem: Principle and Practice (1994), p. 206-208.

Applicant claims compounds of formula I, isomers and their composition as serotonin and norepinephrine reuptake inhibitors.

Determination of the scope and content of the prior art (MPEP 2141.01)

Shephard et al., teach similar compounds and their compositions as serotonin and norepinephrine reuptake inhibitors. See pages 1-2 and example 8.

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the instant invention and that of Shephard et al., is that in compounds of Shephard et al., applicant replaced -CH=CH- with -S- in quinolinyl (Y) ring. Also, applicant claims isomers instead of racemate structure by Shephard et al.

Finding of prima facie obviousness--rational and motivation (MPEP 2142.2413)

However, King teaches that replacement of -CH=CH- with -S- in a ring is expected to produce compounds having similar biological activity (bioisosterism). See page 208, ring

equivalents. See also, *Ex parte Engelhardt*, 208 USPQ 343 (Bd. Pat. App. & Int., 1980); *In re Merck*, 231 USPQ 375 (Fed. Cir. 1986).

However, the racemate of Shephard et al., embraces the isomers. The isomers are not patentable absent unexpected result. *In re Adamson*, 125 USPQ 233 (1960).

Therefore, the instant invention is prima facie obvious from the teachings of Shephard et al., and King. One of ordinary skill in the art would have known to replace -CH=CH- with -S- in a ring, claim the isomers at the time the instant invention was made. The motivation is from knowing that -CH=CH- and -S- are bioisosteres equivalents, and that one isomer is more active than the other isomer or the racemate.

Alternatively, given the teachings of the prior arts, it would have been obvious to try above substitutions and claimed the isomers at the time the invention was made.

When there is motivation

to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under [35 USC] 103.

KSR Int'l Co. v. Teleflex Inc., 127 S.Ct 1727,-----, 82 USPQ2d 1385, 1397 (2007).

Alternatively, applicant has done nothing more than substitutes known bioisosteres equivalents in the compounds of Shephard et al. However, such substitution is obvious from the prior arts. "When a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do

more than yield a predictable result." *United States v. Adams*, 383 U.S. 49, 50-51 (1966). Cited in *KSR Int. Co. v. Teleflex Inc.*, 550 U.S. ----, 82 USPQ2d 1385 (2007). The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR, supra*.

Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 6-7, 22, 34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 31 of copending Application No. 10/533,328 in view of King, *Med Chem: Principle and Practice* (1994), p. 206-208. This is a provisional obviousness-type double patenting rejection.

Applicant claims compounds of formula I, isomers and their composition as serotonin and norepinephrine reuptake inhibitors.

Determination of the scope and content of the prior art (MPEP 2141.01)

In US '328 applicant claims similar compounds and their compositions as serotonin and norepinephrine reuptake inhibitors.

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the instant invention and that of US '328 is that applicant claims a racemate structure instead of the isomers in US '765, and replaced -N= with -CH= in the ring at Y (benzothieno instead of thienopyridyl in US '765).

Finding of prima facie obviousness--rational and motivation (MPEP 2142.2413)

However, King teaches that replacement of -N= with -CH= in a ring is expected to produce compounds having similar biological activity (bioisosterism). See page 208, ring equivalents. See also, *Ex parte Engelhardt*, 208 USPQ 343 (Bd. Pat. App. & Int., 1980); *In re Merck*, 231 USPQ 375 (Fed. Cir. 1986). The specification of US '328, page 4, lines 25-28, states the compound (structure) embraces the individual isomers.

Specification

The specification is objected to due to many pages with missing sections. For example, pages 3, 15, 21, 33 and 39. The specification has not been checked to determine all the bad pages, and applicant may use the public pair-system to ascertain the damage. A replacement specification is hereby required.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

A handwritten signature in black ink, appearing to read 'Solola', with a stylized flourish extending to the left.

TAOFIQ SOLOLA
PRIMARY EXAMINER
Group 1625

November 20, 2007